



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10757]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: On March 13, 2020, the President declared a national emergency in response to the public health emergency (PHE) caused by the SARS-CoV-2 virus, otherwise known as COVID-19. The CARES Act was published in response to the PHE that requires “every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 shall report the results from each such test.” The September 2, 2020 interim final rule with comment (CMS-3401-IFC) requires laboratories to report SARS-CoV-2 test results in a manner and frequency specified by the Secretary. Consistent with the CARES Act laboratory reporting requirements, CMS made modifications to the CLIA regulations to meet the SARS-CoV-2 test result reporting provisions related to the Secretary’s Public Health Emergency declaration with respect to COVID-19.

DATES: Comments must be received by **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted within 15 days in any one of the following ways:

1. *Electronically*. You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.

2. *By regular mail*. You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the PRA, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed ICR. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this ICR including the necessity and utility of the proposed ICR for the proper performance of the agency’s functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Contents

This notice sets out a summary of the use and burden associated with the following ICR. More detailed information can be found in the collection’s supporting statement and associated materials (see ADDRESSES).

CLIA Collection of Information Requirements Related to SARS-CoV-2 Test Results Reporting

Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public: submit reports, keep records, or provide information to a third party. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

Information Collection

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* CLIA Collection of Information Requirements Related to SARS-CoV-2 Test Results Reporting; *Use:* In order to be in compliance with the new CLIA mandatory SARS-CoV-2 test results reporting requirements, laboratories will need to develop a mechanism to track, collect, and report test results as well as update policies and procedures. In addition, Accreditation Organizations (AOs) and Exempt States (ESs) will need to update laboratory standards to reflect the reporting requirements and update policies and procedures related to reporting laboratories that do not report test results as required.

The CDC has an information collection request (OMB Control Number 0920-1299) in order to collect laboratory data related to the COVID-19 Pandemic Response. The CMS package (ICR) is for laboratory implementation and CMS monitoring of compliance with the CMS-3401-IFC CLIA-certified laboratory reporting requirements.

The information collected by the Centers for Medicare and Medicaid Services (CMS) or its

designee, such as a CMS agent or CMS approved laboratory accreditation organization, when conducting inspections will be used to determine a laboratory's compliance with the CLIA SARS-CoV-2 test result reporting requirements. During an on-site survey, the Condition-level laboratory requirement at 42 CFR §§493.41 and 493.1100(a) are assessed for compliance. The information is used by CMS in determining appropriate Civil Money Penalties (CMPs) when laboratories fail to report as required. *Form Number:* CMS-10757 (OMB control number: 0938–NEW); *Frequency:* Daily; *Affected Public:* Private Sector Not-for-profit institutions and State, Local and Tribal Governments; *Number of Respondents:* 77,033; *Total Annual Responses:* 308,114; *Total Annual Hours:* 1,386,873 (For policy questions regarding this collection contact Sarah Bennett at 410–786–3354.)

Dated: October 30, 2020.

William N. Parham, III,
Director, Paperwork Reduction Staff,
Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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